REMARKS

Claims 1, 4, 10, 13, 20, 22, 23, 25, 27, and 28 have been amended. Claims 6, 15, 24, and 29 have been canceled. Claims 1-5, 7-14, 16-23, 25-28, and 30 remain pending.

An Information Disclosure Statement citing further art references is being submitted with this paper. Acknowledgement of the Information Disclosure Statement and entry of the cited art references on the record are requested.

Claims 20-24 stand rejected under the judicially created doctrine of double patenting over Claims 1, 2, 4, 6, and 7 of commonly assigned U.S. Patent No. 6,277,072. A Terminal Disclaimer is enclosed. Withdrawal of the rejection for double patenting is requested.

Claims 25-30 stand rejected under the judicially created doctrine of double patenting over Claims 12, 13, 15, 17, 18, 23, 24, and 26-28 of commonly assigned U.S. Patent No. 6,277,072. A Terminal Disclaimer is enclosed. Withdrawal of the rejection for double patenting is requested.

Claims 3, 4, 6, 10, 13, 15, 22, 23, 27, and 28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The claims have been amended responsive to the indefiniteness rejection, as follows.

The term "a feedback module" refers to different elements in Claims 3 and 4. Claims 3 and 4 both depend separately on Claim 1. Proper antecedent basis is stated. MPEP 2173.05(e).

The terms "reference feedback" and "updated feedback" can be respectively read as "reference measures" and "updated measures" in Claims 4, 13, 22, and 27. Claims 4, 13, 22, and 27 have been amended to clarify the terms.

The term "patient status indicator" in Claims 13 and 15 refer to the same element. Claims 4, 6, 13, and 15 have been amended to clarify antecedent basis.

The term "a database module" refers to different elements in Claims 4 and 6. Claims 4 and 6 both depend separately on Claim 1. Proper antecedent basis is stated. MPEP 2173.05(e).

The term "the patient care record" in Claims 23 and 28 refer to the same element recited respectively in Claims 20 and 25. Claims 23 and 28 have been

amended to clarify antecedent basis.

The specific bases for indefiniteness having been addressed, withdrawal of the rejection for indefiniteness is requested.

Claims 1-5 and 10-14 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,724,983, to Selker et al (Selker I). Under 35 U.S.C. 102(b), a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131. Applicant traverses the rejection. The Selker I reference fails to describe, either expressly or inherently, each and every claim element of, and therefore does not anticipate, Claims 1-5 and 10-14.

Selker I discloses continuous monitoring using a predictive instrument, preferably by computing a probability of a medical outcome or diagnosis, such as an acute cardiac ischemia, based on monitored clinical features (Col. 1, line 61-Col. 2, line 3). The Selker I device is preferably embodied as a cardiac patient monitoring system, which includes a 12-lead electrocardiograph, waveform analyzer, predictive instrument, and control module (Col. 2, lines 49-52). The waveform analyzer is programmed to analyze ECG waveforms, such as S-T segments, Q waves, and T waves, and to recognize the presence of certain characteristics that are particularly indicative of a cardiac condition (Col. 2, lines 54-60). The device can be programmed to identify the location of a myocardial infarction and can compute the probability that the patient has an acute (sudden) cardiac ischemia (Col. 3, lines 30-42; Col. 4, lines 14-17). Furthermore, Selker I can periodically compute and monitor for changes to any probability of a serious cardiac condition, in addition to the probability of an acute cardiac ischemia (Col. 8, lines 16-28).

Succinctly stated, Selker I discloses computing and monitoring an acute medical condition, such as cardiac ischemia, that has a sudden and rapid onset. Such conditions are readily detectable through a comparison of ECG waveforms to cardiac event probabilities through regression testing (Col. 6, lines 7-33). Selker I fails to teach or suggest on-going patient monitoring based on information recorded on a substantially continuous basis. Instead, the Selker I

device first compares a computed change statistic Δ_p to a first threshold $T_{\Delta 1}$, which represents an alarm threshold or threshold for clinical activity, and enters an idle state for a pre-selected delay period. The device then compares the absolute value of Δ_p to a lower threshold $T_{\Delta 2}$, which defines a level below which a change in a patient's condition is considered to be not large enough to be clinically significant, and again returns to an idle state for a pre-selected period of time (Col. 4, line 45-Col. 5, line 29). The two pre-selected idle periods break any continuity in patient monitoring performed by Selker I.

Selker I fails to teach or suggest continuously determining and following an on-going medical condition and, in fact, teaches away from diagnosing and monitoring an absence, onset, progression, regression, and status quo of patient status. Claims 1 and 10 have been amended to emphasize this distinction. Support can be found in Applicant's specification on page 22, lines 8-13. Claims 1 and 10 have also been amended to respectively incorporate the limitations of cancelled Claims 6 and 15 and now recite a database storing patient care records with each record containing one or more physiological measures regularly recorded by an implantable medical device. Support can be found in the specification on page 11, line 3-12. Selker I does not teach or suggest recording physiological measures utilizing an implantable medical device. Therefore, the Selker I reference does not teach all the claim limitations.

Claims 2-5 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claim 11-14 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, the Selker I reference fails to describe, either expressly or inherently, each and every claim element of Claims 1-5 and 10-14. As Selker I fails to anticipate Claims 1-5 and 10-14, withdrawal of the rejection for anticipation is requested.

Claims 1-5 and 10-14 also stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,155,267, to Nelson. Applicant traverses the

rejection. The Nelson reference fails to describe, either expressly or inherently, each and every claim element of, and therefore does not anticipate, Claims 1-5 and 10-14.

Nelson discloses an implantable medical device monitoring method providing at least one sensor output signal to an implantable medical device and providing chronic data representative of at least one physiological parameter based on the sensor output signal (Abstract). A baseline is established using the chronic data provided in an initial sample time period (Col. 2, lines 57-59). The chronic data is monitored to detect a change in state of the physiological parameter relative to the baseline (Col. 2, lines 52-64). Data associated with detected changes in state is stored within the implantable medical device (Col. 4, lines 53-59). Only detected changes in state are recorded and the chronic data received by the monitoring device is discarded (Col. 4, lines 59-61)

Nelson fails to teach or suggest continuously determining and following an on-going medical condition and, in fact, teaches away from diagnosing and monitoring an absence, onset, progression, regression, and status quo of patient status, as chronic data is discarded and unavailable for following an on-going medical condition. Claims 1 and 10 have been amended to emphasize this distinction. Support can be found in Applicant's specification on page 22, lines 8-13. Claims 1 and 10 have also been amended to respectively incorporate the limitations of cancelled Claims 6 and 15 and now recite a database storing patient care records with each record containing one or more physiological measures regularly recorded by an implantable medical device. Support can be found in the specification on page 11, line 3-12. Nelson does not teach or suggest using a database for storing patient care records independent of the implantable medical device. Therefore, the Nelson reference does not teach all the claim limitations.

Claims 2-5 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claim 11-14 are dependent on Claim 10 and is patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, the Nelson reference fails to described, either expressly or

inherently, each and every claim element of Claims 1-5 and 10-14. As Nelson fails to anticipate Claims 1-5 and 10-14, withdrawal of the rejection for anticipation is requested.

Claim 6, 15, and 20-29 stand rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of U.S. Patent No. 6,168,563, to Brown. To establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings; (2) there must be a reasonable expectation of success; and (3) the combined references must teach or suggest all the claim limitations. MPEP § 2143. Applicant traverses the rejection. Claims 6, 15, 24, and 29 have been cancelled and the rejection of these claims for obviousness has been rendered moot. The Selker I and Brown references, taken either singly or in combination, fail to teach or suggest all the claim limitations and therefore do not render remaining Claims 20-23 and 25-28 obvious.

Brown discloses a system and method for monitoring and managing a health condition of a patient by using a remotely programmable patient-operable apparatus (Abstract). The programmable patient apparatus provides information to the patient about the patient's health condition and interactively monitors the patient health condition by asking the patient questions and by receiving answers to those questions (Col. 14, line 27-Col. 15, line 16). The patient information may include information supplied by a physiological monitoring device such as a blood glucose monitor that is connected to the remotely programmable patient apparatus (Col. 15, lines 40-57).

Claim 20 defines a system for managing a reference baseline of patient information for use in automated patient care. A processing module processes one or more reference physiological measures regularly recorded by an implantable medical device during an initial observation period. A comparison module compares the updated physiological measures in each individual measures set to the reference physiological measures in the reference baseline and identifies any such updated physiological measure substantially non-conforming to the

corresponding reference physiological measure for evaluating an absence, an onset, a progression, a regression, and a status quo of patient status as part of a patient status indicator. A quality of life comparison submodule compares the updated quality of life measures to the reference quality of life measures in the patient care record and identifies any such updated quality of life measure substantially non-conforming to the corresponding reference quality of life measures as part of the patient status indicator. The combination of Selker I and Brown fails to teach or suggest the all the claim limitations. Neither reference teaches or suggests these limitations and, in particular, neither teaches or suggests recording physiological measures utilizing an implantable medical device. Therefore, there would be no suggestion or motivation to modify the references or combine the reference teachings.

Claim 25 defines a method for managing a reference baseline of patient information for use in automated patient care. One or more reference physiological measures regularly recorded by an implantable medical device during an initial observation period are processed. The updated physiological measures in each individual measures set are compared to the reference physiological measures in the reference baseline and any such updated physiological measure substantially non-conforming to the corresponding reference physiological measure are identified for evaluating an absence, an onset, a progression, a regression, and a status quo of patient status as part of a patient status indicator. The updated quality of life measures are compared to the reference quality of life measures in the patient care record and any such updated quality of life measure substantially non-conforming to the corresponding reference quality of life measures are identified as part of the patient status indicator. The combination of Selker I and Brown fails to teach or suggest the all the claim limitations. Neither reference teaches or suggests these limitations and, in particular, neither teaches or suggests recording physiological measures utilizing an implantable medical device. Therefore, there would be no suggestion or motivation to modify the references or combine the reference teachings.

Claims 20-23 are dependent on Claim 20 and are patentable for the above-

stated reasons, and as further distinguished by the limitations recited therein. Claims 25-28 are dependent on Claim 25 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein.

Accordingly, the Selker I and Brown references, taken as a whole, fail to teach or suggest the claimed subject matter of remaining Claims 20-23 and 25-28. As Selker I and Brown fail to render Claims 20-23 and 25-28 obvious, withdrawal of the rejection for obviousness is requested.

Claims 7-9 and 16-18 stand rejected under 35 U.S.C. 103(a) as being obvious over Selker I in view of U.S. Patent No. 4,852,570, to Levine. Applicant traverses the rejection. The Selker I and Levine references, taken either singly or in combination, fail to teach or suggest all the claim limitations and therefore do not render Claims 7-9 and 16-18 obvious.

As described above with reference to the anticipation rejection of Claims 1-5 and 10-14, the Selker I reference fails to teach or suggest all the claim elements. Claims 7-9 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 16-18 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, the Selker I and Levine references, taken as a whole, fail to teach or suggest the claimed subject matter of Claims 7-9 and 16-18. As Selker I and Levine fail to render Claims 7-9 and 16-18 obvious, withdrawal of the rejection for obviousness is requested.

Claims 19 and 30 are rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of Brown, and further in view of Levine, and further in view of U.S. Patent No. 6,067,466, issued May 23, 2000, to Selker et al. (Selker II). Applicant traverses the rejection. The Selker I, Brown, Levine, and Selker II references, taken either singly or in combination, fail to teach or suggest all the claim limitations and therefore do not render Claims 19 and 30 obvious.

As described above with reference to the anticipation rejection of Claims 1-5 and 10-14, the Selker I reference fails to teach or suggest all the claim elements. Claim 7-9 are dependent on Claim 1 and are patentable for the above-

stated reasons, and as further distinguished by the limitations recited therein. Claims 16-18 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, the Selker I, Brown, Levine, and Selker II references, taken as a whole, fail to teach or suggest the claimed subject matter of Claims 7-9 and 16-18. As Selker I, Brown, Levine, and Selker II references fail to render Claims 7-9 and 16-18 obvious, withdrawal of the rejection for obviousness is requested.

The abstract stands subject to objection on formal grounds and has accordingly been corrected. Withdrawal of the objection of the abstract is requested.

The prior art made of record and not relied upon has been reviewed by the applicant and is considered to be no more pertinent than the prior art references already applied.

Claims 1-5, 7-14, 16-23, 25-28, and 30 are believed to be in condition for allowance. Entry of the foregoing amendments is requested and a Notice of Allowance is earnestly solicited. Please contact the undersigned at (206) 381-3900 regarding any questions or concerns associated with the present matter.

Respectfully submitted,

Dated: August 12, 2003

By: _____
Patrick J.S. Inouye, Esq.
Reg. No. 40,297

Law Offices of Patrick J.S. Inouye
810 Third Avenue, Suite 258
Seattle, WA 98104

Telephone: (206) 381-3900
Facsimile: (206) 381-3999